U.S.S.N.: 10/613,975 Filed: July 3, 2003

INFORMATION DISCLOSURE STATEMENT

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Publications

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/KS/

ALONSO, et al., "Determinants of release rate of tetanus vaccine from polyester microspheres," *Pharm. Res.* 10(7): 945-953 (1993).

ANCHORDOQUY & KOE, "Physical stability of nonviral plasmid-based therapeutics," J. Pharm. Science. 89(3): 289-296 (2000).

ARORA & LEPPLA, "Residues 1-254 of anthrax toxin lethal factor are sufficient to cause cellular uptake of fused polypeptides," J. Biol. Chem 268: 3334-3341 (1993).

BENNS & KIM, "Tailoring new gene delivery designs for specific targets," J. Drug Target. 8(1): 1-12 (2000).

CAPAN, et al., "Preparation and characterization of poly(D,L-lactide-co-glycolide) microspheres for controlled release of poly (L-lysine) complexed plasma DNA," *Pharm. Res.* 16(4): 509-513 (1999).

CHICKERING & MATHIOWITZ, "Bioadhesive microspheres: I. A novel electrobalance-based method to study adhesive interactions between individual microspheres and intestinal mucosa," *J. Control. Rel.* 34: 251-262 (1995).

COHEN, et al., "Sustained delivery and expression of DNA encapsulated in polymeric nanoparticles," Gene Ther. 7: 1896-1905 (2000).

DAVIS, "Polymeric systems for vaccine delivery," Res. Immunol. 149: 49-52 (1998).

DEHAAN, et al., "The role of ADP-ribosylation and G_{M1}-binding activity in the mucosal immunogenicity and adjuvanticity of the *Escherichia coli* heat-labile enterotoxin and *Vibrio cholerae* cholera toxin," *Immun. Cell Biol.* 76: 270-279 (1998).

DENNIS, et al., "Tularemia as a biological weapon," JAMA 285(21): 2763-2773 (2001).

DOOLAN, et al., "Circumventing genetic restriction of protection against malaria with multigene DNA immunization: CD8⁺ T cell-, Interferon γ -, and nitric oxide-dependent immunity," *J. Exp. Med.* 183: 1739-1746 (1996).

DUESBERY, et al., "Proteolytic inactivation of MAP-kinase-kinase by anthrax lethal factor," *Science* 280: 734-737 (1998).

ELDRIDGE, et al., "Biodegradable and biocompatible poly(DL-lactide-co-glycolide) microspheres as an adjuvant for staphylococcal enterotoxin B toxoid which enhances the level of toxin-neutralizing antibodies," *Infect. Immunity.* 59: 2978-2986 (1991).

ELKINS, et al., "Rapid generation of specific protective immunity to Francisella tularensis," Infect. Immun 60(11): 4571-4577 (1992).

10/613,975

Filed:

July 3, 2003

INFORMATION DISCLOSURE STATEMENT

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ELKINS, et al., "Bacterial DNA containing CpG motifs stimulates lymphocyte-dependent protection of mice against lethal infection with intracellular bacteria," *J. Immunol.* 162(4): 2291-2298 (1999).

ELKINS, et al., "Introduction of *Francisella tularensis* at skin sites induces resistance to infection and generation of protective immunity," *Microb. Pathogen.* 13(5): 417-421 (1992).

EL-MADHUN, et al., "Systemic and mucosal immune responses in young children and adults after parenteral influenza vaccination," J. Infect. Dis 178(4): 933-939 (1998).

ERMAK, et al., "Uptake and trasnport of copolymer biodegradable microspheres by rabbit Peyer's patch M cells," *Cell Tiss. Res.* 279: 433-436 (1995).

GARDNER, et al., "Chromosome 2 sequence of the human malaria parasite *Plasmodium* falciparum," Science 282: 1126–1132 (1998).

GILLEY, et al., "Microencapsulation and its application to vaccine development," Proc. 19th Int. Symp. Control. Rel. Bioact. Mater. 19: 110-111 (1992).

GORDON, et al., "Proteolytic activation of bacterial toxins by eukaryotic cells is performed by furin and by additional cellular proteases," *Infect. Immun* 63: 82-87 (1995).

GU, et al., "Protection against anthrax toxin by vaccination with a DNA plasmid encoding anthrax protective antigen," *Vaccine* 17: 340-344 (1999).

GUPTA, et al., "Involvement of residues 147VYYEIGK153 in binding of lethal factor to protective antigen of *Bacillus anthracis*," *Biochem. Biophys. Res. Commun.* 280: 158-163 (2001).

GUY, et al., "Effects of the nature of adjuvant and site of parenteral immunization on the serum and mucosal immune responses induced by a nasal boost with a vaccine alone," Clin. Diagn. Lab. Immunol. 5(5): 732-736 (1998).

GUY, et al., "Systemic immunization with urease protects mice against *Helicobacter pylori* infection," *Vaccine* 16(8): 850-856 (1998).

GUY, et al., "Comparison between targeted and untargeted systemic immunizations with adjuvanted urease to cure *Helicobacter pylori* infection in mice," *Vaccine* 17: 1130-1135 (1999).

HOFFMAN, et al., "Toward clinical trials of DNA vaccines against malaria," *Immun. Cell Biol.* 75: 376-381 (1997).

HSU, et al., "Effect of polymer foam morphology and density on kinetics of *in vitro* controlled release of isoniazid from compressed foam matrices," *J. Biomed. Mat. Res.* 35: 107-116 (1997).

/KS/

10/613,975

Filed:

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/KS/

INFORMATION DISCLOSURE STATEMENT

IVINS, et al., "Recent advances in the development of an improved human anthrax vaccine," Eur. J. Epidemiol. 4: 12-19 (1988).

KAWABATA, et al., "The fate of plasmid DNA after intravenous injection in mice: involvement of scavenger receptors in its hepatic uptake," *Pharm. Res.* 12(6): 825-830 (1995).

KLIMPEL, et al., "Anthrax toxin protective antigen is activated by a cell surface protease with the sequence specificity and catalytic properties of furin," *Proc. Natl. Acad. Sci., USA* 89: 10277-10281 (1992).

KLINMAN, et al., "Repeated administration of synthetic oligodeoxynucleotides expressing CpG motifs provides long-term protection against bacterial infection," *Infect. Immunol.* 67: 5658-5663 (1999).

KRIEG, et al., "CpG DNA induces sustained 1L-12 expression in vivo and resistance to Listeria monocytogenes challenge," J. Immunol. 161: 2428-2434 (1998).

KUPER, et al., "The role of nasopharyngeal lymphoid tissue," *Immunol. Today* 13(6): 219-224 (1992).

LABHASETWAR, et al., "A DNA controlled-release coating for gene transfer: transfection in skeletal and cardiac muscle," *J. Pharm. Science* 87(11): 1347-1350 (1998).

LE, et al., "Safety, tolerability and humoral immune responses after intramuscular administration of a malaria DNA vaccine to healthy adult volunteers," *Vaccine* 18: 1893-1901 (2000).

LEE, et al., "Immunization of rhesus monkeys with a mucosal prime, parenteral boost strategy protects against infection with *Helicobacter pylori*," *Vaccine* 17: 3072-3082 (1999).

LEPPLA, et al., "Proteolytic activation of anthrax toxin bound to cellular receptors," in <u>Bacterial protein toxins</u> (Fehrenbach, et al., eds) pp. 111-112, Gustav Fischer: New York (1988).

LEPPLA, "Anthrax toxin edema factor: a bacterial adenylate cyclase that increases cyclic AMP concentrations in eukaryotic cells," *Proc. Natl. Acad. Sci. USA* 79: 3162-3166 (1982).

LITTLE & KNUDSON, "Comparative efficacy of *Bacillus anthracis* live spore vaccine and protective antigen vaccine against anthrax in the guinea pig," *Infect. Immun.* 52(2): 509-512 (1986).

LUNSFORD, et al., "Tissue distribution and persistence in mice of plasmid DNA encapsulated in a PLGA-based microsphere delivery vehicle," *J. Drug. Target.* 8(1): 39-50 (2000).

LUO, et al., "Synthetic DNA delivery systems," Nature Biotech 18: 33-37 (2000).

/KS/

10/613,975

July 3, 2003

INFORMATION DISCLOSURE STATEMENT

/KS/

MCGHEE, et al., "The mucosal immune system: from fundamental concepts to vaccine development," Vaccine 10(2): 75-88 (1992).

MIKESELL, et al., "Evidence for plasmid-mediated toxin production in Bacillus anthracis," Infect. Immun. 39: 371-376 (1983).

MILNE, et al., "Anthrax protective antigen forms oligomers during intoxication of mammalian cells," J. Biol. Chem 269(32): 20607-20612 (1994).

NEUTRA, et al., "Antigen sampling across epithelial barriers and induction of mucosal immune responses," Ann. Rev. Immunol. 14: 275-300 (1996).

O'HAGAN, et al., "Controlled release microparticles for vaccine development," Vaccine 9: 768-771 (1991).

O'HAGAN, et al., "Long-term antibody response in mice following subcutaneous immunization with ovalbumin entrapped in biodegradable microparticles," Vaccine 11(9): 965-969 (1993).

PARTIDOS, et al., "Mucosal immunization with a measles virus CTL epitope encapsulated in biodegradable PLG microparticles," J. Imm. Meth. 195: 135-138 (1996).

PEREZ, et al., "Poly(lactic acid)-poly(ethylene glycol) nanoparticles as new carriers for the delivery of plasmid DNA," J. Control. Rel. 75: 211-224 (2001).

PERTMER, et al., "Gene gun-based nucleic acid immunization: elicitation of humoral and cytotoxic T lymphocyte responses following epidermal delivery of nanogram quantities of DNA," Vaccine 13(15): 1427-1430 (1995).

PRICE, et al., "Protection against anthrax lethal toxin challenged by genetic immunization with a plasmid encoding the lethal factor protein," Infect. Immunity. 69(7): 4509-4515 (2001).

SEDEGAH, et al., "Boosting with recombinant vaccinia increases immunogenicity and protective efficacy of malaria DNA vaccine," Proc. Nat. Acad. Sci. USA 95: 7648-7653 (1998).

SEDEGAH, et al., "Improving protective immunity induced by DNA-based immunization: priming with antigen and GM-CSF-encoding plasmid DNA and boosting with antigen-expressing recombinant poxvirus," J. Immun. 164: 5905-5912 (2000).

SINGH, et al., "Controlled delivery of diphtheria toxoid using biodegradable poly(D,Llactide) microcapsules," Pharm. Res. 8: 958-961 (1991).

SMITH, et al., "Induction of secretory immunity with bioadhesive poly (D,L-lactid-coglycolide) microparticles containing Streptococcus sobrinus glucosyltransferase," Oral. Microbiol. Immunol. 15: 124-130 (2000).

/KS/

10/613,975

Filed:

July 3, 2003

INFORMATION DISCLOSURE STATEMENT

/KS/

STOUTE, et al., "A preliminary evaluation of a recombinant circumsporozoite protein vaccine against *Plasmodium falciparum* malaria," N. Engl. J. Med. 336: 86-91 (1997).

THOMASIN, et al., "Tetanus toxoid and synthetic malaria antigen containing poly(lactide)/poly(lactide-co-glycolide) microspheres: importance of polymer degradation and antigen release for immune response," J. Control. Rel. 41: 131-145 (1996).

TINSLEY-BROWN, et al., "Formulation of poly (D,L-lactide-co-glycolic acid) microparticles for rapid plasmid DNA delivery," J. Control. Rel. 66: 229-241 (2000).

TRANTOLO, et al., "Delivery of vaccines by biodegradable polymeric microparticles with bioadhesion properties," *Proc.* 5th World Congress, Chem. Eng. (1996).

VISSCHER, et al., "Biodegradation of and tissue reaction to 50:50 poly(DL-lactide-coglycolide) microcapsules," J. Biomed. Mat. Res. 19: 349-365 (1985).

WANG, et al., "Simultaneous induction of multiple antigen-specific cytotoxic T lymphocytes in nonhuman primates by immunization with a mixture of four *Plasmodium falciparum* DNA plasmids," *Infect. Immunity*. 66(9): 4193-4202 (1998).

WEINER, "Oral tolerance," Proc. Natl. Acad. Sci. USA 91: 10762-10765 (1994).

WOLFF, et al., "Direct gene transfer into mouse muscle in vivo," *Science* 247: 1465-1468 (1990).

WU & RUSSELL, "Nasal lymphoid tissue, intranasal immunization, and compartmentalization of the common mucosal immune system," *Immunol. Res.* 16(2): 187-201 (1997).

YEE, et al., "Loss of either CD4⁺ or CD8⁺ cells does not affect the magnitude of protective immunity to an intracellular pathogen, *Fancisella tularensis* strain LVS," *J. Immunol*. 157: 5042-5048 (1996).

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			First Named Inventor	Donald L. Wise		
i			Group Art Unit	1642		
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			U.S. PATENT DOCUM	ENTS	
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/KS/		5,456,917	Wise, et al.	10-10-1995	
		 			
		 			
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/KS/		ALONSO, et al., "Determinants of release rate of tetanus vaccine from polyester microspheres," <i>Pharm. Res.</i> 10(7): 945-953 (1993).	
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/KS/		BENNS & KIM, "Tailoring new gene delivery designs for specific targets," J. Drug Target. 8(1): 1-12 (2000).	
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/KS/		DAVIS, "Polymeric systems for vaccine delivery," Res. Immunol. 149: 49-52 (1998).	_
/KS/		DEHAAN, et al., "The role of ADP-ribosylation and G _{M1} -binding activity in the mucosal immunogenicity and adjuvanticity of the <i>Escherichia coli</i> heat-labile enterotoxin and <i>Vibrio cholerae</i> cholera toxin," <i>Immun. Cell Biol.</i> 76: 270-279 (1998).	
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/KS/	-	KUPER, et al., "The role of nasopharyngeal lymphoid tissue," Immunol. Today 13(6): 219-224 (1992).	
/KS/		LABHASETWAR, et al., "A DNA controlled-release coating for gene transfer: transfection in skeletal and cardiac muscle," J. Pharm. Science 87(11): 1347-1350 (1998).	
/KS/		LE, et al., "Safety, tolerability and humoral immune responses after intramuscular administration of a malaria DNA vaccine to healthy adult volunteers," Vaccine 18: 1893-1901 (2000).	
/KS/	-	LEE, et al., "Immunization of rhesus monkeys with a mucosal prime, parenteral boost strategy protects against infection with Helicobacter pylori," Vaccine 17: 3072-3082 (1999).	
/KS/		LEPPLA, et al., "Proteolytic activation of anthrax toxin bound to cellular receptors," in <u>Bacterial protein toxins</u> (Fehrenbach, et al., eds) pp. 111-112, Gustav Fischer: New York (1988).	
/KS/		LEPPLA, "Anthrax toxin edema factor: a bacterial adenylate cyclase that increases cyclic AMP concentrations in eukaryotic cells," <i>Proc. Natl. Acad. Sci. USA</i> 79: 3162-3166 (1982).	
/KS/		LITTLE & KNUDSON, "Comparative efficacy of <i>Bacillus anthracis</i> live spore vaccine and protective antigen vaccine against anthrax in the guinea pig," <i>Infect. Immun.</i> 52(2): 509-512 (1986).	

Examiners		Date Considered 04/26/2007
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INFORMATION DISCLOSUF STATEMENT BY APPLICAN (use as many sheets as necessary)		10/613,975	
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•	First Named Inventor	Donald L. Wise	
	First Named Inventor Group Art Unit	Donald L. Wise 1642	
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		OTHER ART NON PATENT LITERATURE DOCUMENTS	
Examiner's Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	Τ²
/KS/		LUNSFORD, et al., "Tissue distribution and persistence in mice of plasmid DNA encapsulated in a PLGA-based microsphere delivery vehicle," <i>J. Drug. Target.</i> 8(1): 39-50 (2000).	
/KS/		LUO, et al., "Synthetic DNA delivery systems," Nature Biotech 18: 33-37 (2000).	
/KS/		MCGHEE, et al., "The mucosal immune system: from fundamental concepts to vaccine development," Vaccine 10(2): 75-88 (1992).	
/KS/		MIKESELL, et al., "Evidence for plasmid-mediated toxin production in Bacillus anthracis," Infect. Immun. 39: 371-376 (1983).	
/KS/		MILNE, et al., "Anthrax protective antigen forms oligomers during intoxication of mammalian cells," <i>J. Biol. Chem</i> 269(32): 20607-20612 (1994).	
/KS/		NEUTRA, et al., "Antigen sampling across epithelial barriers and induction of mucosal immune responses," Ann. Rev. Immunol. 14: 275-300 (1996).	
/KS/		O'HAGAN, et al., "Controlled release microparticles for vaccine development," Vaccine 9: 768-771 (1991).	
/KS/		O'HAGAN, et al., "Long-term antibody response in mice following subcutaneous immunization with ovalbumin entrapped in biodegradable microparticles," <i>Vaccine</i> 11(9): 965-969 (1993).	
/KS/		PARTIDOS, et al., "Mucosal immunization with a measles virus CTL epitope encapsulated in biodegradable PLG microparticles," J. Imm. Meth. 195: 135-138 (1996).	
/KS/		PEREZ, et al., "Poly(lactic acid)-poly(ethylene glycol) nanoparticles as new carriers for the delivery of plasmid DNA," J. Control. Rel. 75: 211-224 (2001).	

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	•	•	••	Filing Date	July 3, 2003		
				First Named Inventor	Donald L. Wise		
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initials*	No.1	item (bock, magazine, joumal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	
/KS/		PERTMER, et al., "Gene gun-based nucleic acid immunization: elicitation of humoral and cytotoxic T lymphocyte responses following epidermal delivery of nanogram quantities of DNA," Vaccine 13(15): 1427-1430 (1995).	
/KS/		PRICE, et al., "Protection against anthrax lethal toxin challenged by genetic immunization with a plasmid encoding the lethal factor protein," <i>Infect. Immunity.</i> 69(7): 4509-4515 (2001).	
/KS/		SEDEGAH, et al., "Boosting with recombinant vaccinia increases immunogenicity and protective efficacy of malaria DNA vaccine," <i>Proc. Nat. Acad. Sci. USA</i> 95: 7648-7653 (1998).	-
/KS/		SEDEGAH, et al., "Improving protective immunity induced by DNA-based immunization: priming with antigen and GM-CSF-encoding plasmid DNA and boosting with antigen-expressing recombinant poxvirus," J. Immun. 164: 5905-5912 (2000).	
/KS/	•	SINGH, et al., "Controlled delivery of diphtheria toxoid using biodegradable poly(D,L-lactide) microcapsules," <i>Pharm. Res.</i> 8: 958-961 (1991).	
/KS/		SMITH, et al., "Induction of secretory immunity with bioadhesive poly (D,L-lactid-co-glycolide) microparticles containing Streptococcus sobrinus glucosytransferase," Oral. Microbiol. Immunol. 15: 124-130 (2000).	
/KS/		STOUTE, et al., "A preliminary evaluation of a recombinant circumsporozoite protein vaccine against <i>Plasmodium</i> falciparum malaria," <i>N. Engl. J. Med.</i> 336: 86-91 (1997).	
/KS/		THOMASIN, et al., "Tetanus toxoid and synthetic malaria antigen containing poly(lactide)/poly(lactide-co-glycolide) microspheres: importance of polymer degradation and antigen release for immune response," <i>J. Control. Rel.</i> 41: 131-145 (1996).	
/KS/		TINSLEY-BROWN, et al., "Formulation of poly (D,L-lactide-co-glycolic acid) microparticles for rapid plasmid DNA delivery," J. Control. Rel. 66: 229-241 (2000).	
/KS/		TRANTOLO, et al., "Delivery of vaccines by biodegradable polymeric microparticles with bloadhesion properties," Proc. 5" World Congress, Chem. Eng. (1996).	

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/KS/		VISSCHER, et al., "Biodegradation of and tissue reaction to 50:50 poly(DL-lactide-co-glycolide) microcapsules," J. Biomed. Mat. Res. 19: 349-365 (1985).	
/KS/		WANG, et al., "Simultaneous induction of multiple antigen-specific cytotoxic T lymphocytes in nonhuman primates by immunization with a mixture of four <i>Plasmodium falciparum</i> DNA plasmids," <i>Infect. Immunity</i> . 66(9): 4193-4202 (1998).	
/KS/	_	WEINER, "Oral tolerance," <i>Proc. Natl. Acad. Sci. USA</i> 91: 10762-10765 (1994).	
/KS/		WOLFF, et al., Direct gene transfer into mouse muscle in vivo," Science 247: 1465-1468 (1990).	•
/KS/		WU & RUSSELL, "Nasal lymphoid tissue, intranasal immunization, and compartmentalization of the common mucosal immune system," <i>Immunol. Res.</i> 16(2): 187-201 (1997).	
/KS/		YEE, et al., "Loss of either CD4" or CD8" cells does not affect the magnitude of protective immunity to an intracellular pathogen, Fancisella tularensis strain LVS," J. Immunol. 157: 5042-5048 (1996).	
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